

No. 2023-1169

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**United States Court of Appeals for the Federal Circuit**

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AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LIMITED, MOCHIDA  
PHARMACEUTICAL CO., LTD.,

*Plaintiffs-*

*Appellants v.*

HIKMA PHARMACEUTICALS USA INC., HIKMA PHARMACEUTICALS PLC,  
*Defendants-Appellees*

HEALTH NET LLC,  
*Defendant*

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*APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT  
OF DELAWARE,  
CASE NO. 1:20-cv-01630-RGA-JLH, JUDGE RICHARD G. ANDREWS*

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**MOTION OF THE ASSOCIATION FOR ACCESSIBLE  
MEDICINES FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN  
SUPPORT OF HIKMA'S PETITION FOR REHEARING EN BANC**

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September 5, 2024

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## CERTIFICATE OF INTEREST

Counsel for *Amicus Curiae* Association for Accessible Medicines certifies the following:

1. **Represented Entities.** Fed. Cir. R. 47.4(a)(1). Provide the full names of all entities represented by undersigned counsel in this case:

Association for Accessible Medicines.

2. **Real Party in Interest.** Fed. Cir. R. 47.4(a)(2). Provide the full names of all parties in interest for the entities. Do not list the real parties if they are the same as the entities:

N/A

3. **Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3). Provide the full names of all parent corporations for entities and all publicly held companies that own 10% or more stock in the entities:

N/A

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

N/A

5. **Related Cases.** Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b):

N/A

- 6. Organizational Victims and Bankruptcy Cases.** Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

N/A

September 5, 2024

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## MOTION FOR LEAVE

The Association for Accessible Medicines (“AAM”) respectfully moves for leave to file the accompanying brief in support of Hikma’s petition for rehearing en banc, pursuant to Fed. R. App. P. 29(b)(2), Fed. Cir. R. 27, and Fed. Cir. R. 35(g)(1). Appellee consents to, and Appellant does not oppose AAM’s filing of this brief.

Amicus curiae is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM’s members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM’s core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines.

AAM regularly participates in litigation as *amicus curiae*, including in several cases concerning the skinny label provisions at issue in this matter. An amicus brief on this topic is desirable because the panel’s decision affects AAM’s members’ ability to rely on section viii carve-outs to develop and market generic medicines.

For the foregoing reasons, AAM respectfully requests that this Court grant leave to participate as *amicus curiae* and to file the accompanying brief in support

of Hikma's petition for rehearing en banc.

Respectfully submitted,

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Dated: September 5, 2024

**CERTIFICATE OF SERVICE**

I certify that true and correct copies of the foregoing *Motion for Leave to File Brief as Amicus Curiae in Support of Hikma's Petition for Rehearing En Banc* were served on September 5, 2024 on all counsel of record by the CM/ECF system.

September 5, 2024

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## **CERTIFICATE OF COMPLIANCE**

1. I certify that the foregoing Motion for Leave to File Brief as Amicus Curiae in Support of Hikma's Petition for Rehearing En Banc complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d)(2) because it contains 213 words, excluding the accompanying documents authorized by Federal Rule of Appellate Procedure 27(a)(2)(B).

2. The motion complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in 14-point Times New Roman, a proportionally spaced typeface, using Microsoft Word.

September 5, 2024

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